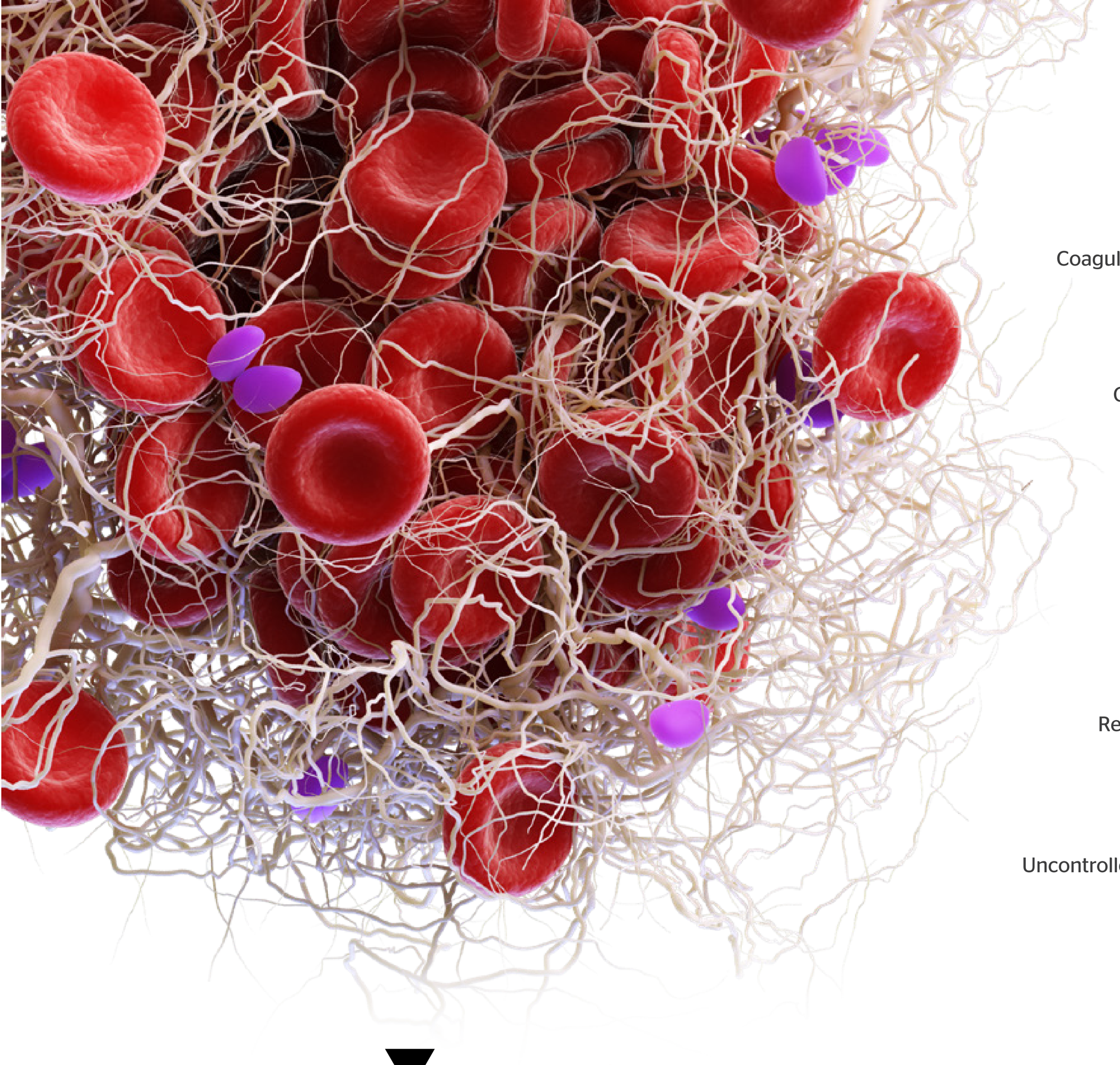

Anticoagulants /
Chronic antiplatelet therapies

Coagulopathies

Certain chemotherapies

Renal / Liver failure

Revision surgery / Adhesions

Uncontrolled diabetes

VERASEAL™ Solutions for Sealant

(Human Fibrinogen, Human Thrombin)

Delivers a reliable fibrin clot when your patient can't.[1,2¥]

The risk of potential bleeding complications calls for a reliable fibrin clot that is effective independent of the patient coagulation profile — especially in high-risk patients.[3,4*]

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Shaping the future of surgery

For more information ...

Call 0800 864 060, refer to the product Instructions for Use, or contact your local Ethicon Biosurgery Sales Specialist.

VeraSeal™ Solutions for sealant (human fibrinogen/human thrombin)
Abbreviated Prescribing Information (API)

Please read Summary of Product Characteristics (SmPC) for full product information before prescribing.

Composition
Component 1: Human fibrinogen 80 mg/ml
Component 2: Human thrombin 500 IU/ml

Therapeutic Indications:
VeraSeal™ is indicated as supportive treatment in adults where standard surgical techniques are insufficient:
-for improvement of haemostasis.
-as suture support in vascular surgery.

CONTRAINDICATIONS
VeraSeal™ must not be applied intravascularly.
Hypersensitivity to the active substance or to any of the excipients listed in SmPC. VeraSeal™ must not be used for the treatment of severe or brisk arterial bleeding. Spray application of VeraSeal™ must not be used in endoscopic (intraluminal) procedures. This medicinal product must not be mixed with other medicinal products.

Posology & administration
The use of VeraSeal™ is restricted to experienced surgeons who have been trained in the use of this medicinal product.
The volume of VeraSeal™ to be applied and the frequency of application should always be oriented towards the underlying clinical needs for the patient. The initial volume of the product to be applied at a chosen anatomic site or target surface area should be sufficient to entirely cover the intended application area. The application can be repeated, if necessary. The safety and efficacy of VeraSeal™ in children aged 0 to 18 years has not yet been established.

WARNINGS AND PRECAUTIONS
For epilesional use only.
Life threatening thromboembolic complications may occur if the preparation is unintentionally applied intravascularly.
VeraSeal™ spray application should only be used if it is possible to accurately judge the spray distance, especially during laparoscopy.
When using accessory tips, the instructions for use of the tips should be followed.
Before administration of VeraSeal™, care must be taken that the parts of the body outside the desired application area are suiciently protected (covered) to prevent tissue adhesion at undesired sites.
VeraSeal™ should be applied as a thin layer. Excessive clot thickness may negatively interfere with the product's efficacy and the wound healing process.
As with any protein product, allergic type hypersensitivity reactions are possible.
When medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

Undesirable effects
Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the application site, bronchospasm, chills, flushing, generalized urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing) may occur in rare cases in patients treated with fibrin sealant/haemostatic products. In isolated cases, these reactions have progressed to severe anaphylaxis. Such reactions may especially be seen, if the preparation is applied repeatedly, or administered to patients known to be hypersensitive to constituents of the product. Antibodies against components of fibrin sealant/haemostatic products may occur rarely. Inadvertent intravascular injection could lead to thromboembolic event and disseminated intravascular coagulation (DIC), and there is also a risk of anaphylactic reaction (Please refer to full SmPC).
For safety information with respect to transmissible agents, please refer to full SmPC.
The most common adverse reactions (frequencies of ≥1/100 to <1/10) were nausea, procedural pain and pruritus.

Pregnancy and Breast Feeding
The safety of fibrin sealant/haemostatic products for use in human pregnancy or breast-feeding has not been established in controlled clinical trials. Therefore, the product should be administered to pregnant and breast-feeding women only if clearly needed.

SUPPLY CLASSIFICATION:
Medicinal product (biologic) subject to restricted medical prescription.

MA HOLDER: Instituto Grifols, S.A., Can Guasc, 2 - Parets del Vallès, E-08150 Barcelona, Spain

MA NUMBER(S):

EEU/1/17/1239/001 2 ml, EU/1/17/1239/002 4 ml, EU/1/17/1239/003 6 ml, EU/1/17/1239/004 10 ml

DATE OF PREPARATION: September 2020

COST: £172.66 (4ml), £389.89 (10ml)

PHARMACOVIGILANCE:

UK: Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Ireland: Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin 2. Telephone 353-1-6764971, Fax 353-1-6762517, e-mail: medsafety@hpra.ie Website: www.hpra.ie

Adverse events should also be reported to Instituto Grifols, S.A. by email:gds@grifols.com

150000-200915 UK

*Reliable based on reproducible clot formation compared to control. Nenezic: Ratio of patient proportion meeting primary end point is 95% (P<0.001). Bjelovic: Rate of Hemostasis after 4 min is 92.4%.

*Patients taking anticoagulants and chronic anticoagulant medications

Reference: 1. Bjelovic M, Ayguasonosa J, Kim R, et al. A prospective, randomized, phase III study to evaluate the efficacy and safety of fibrin sealant Grifols as an adjunct to hemostasis as compared to cellulose sheets in hepatic surgery resections. *J Gastrointest Surg.* 2018;22:1939–1949. **2.** Nenezic D. A prospective, single-blind, randomized, phase III study to evaluate the safety and efficacy of Fibrin Sealant Grifols as an adjunct to hemostasis compared with manual compression in vascular surgery. *J of Vasc Surg.* 2019;70: 642. **3.** Marietta M. Pathophysiology of bleeding in surgery. *Transplant Proc.* 2006;38(3):812-814. **4.** Saif R, Jacob M, Robinson S, et al. Use of fibrin-based sealants and gelatin-matrix hemostats in laparoscopic liver surgery. *Surg Laparosc Endosc Percutan Tech.* 2011;21(3):131-141.

Before using any medical device/ medicinal product, review all relevant Instructions for Use, Package Inserts or Summary of Product Characteristics, with particular attention to the indications, contraindications, warnings and precautions, undesirable effects and steps for use of the medical device / medicinal product.

Date of Preparation: October 2020